Office Action Summary	Application No.	Applicant(s)
	10/594,826	LAZARUS ET AL.
	Examiner	Art Unit
	Ron Schwadron, Ph.D.	1644

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE *3* MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

1)☐ Responsive to communication(s) filed on _____.

2a)☐ This action is **FINAL**. 2b)☒ This action is non-final.

3)☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

4)☒ Claim(s) *1-6,8-11,16-25,27-30,33-39 and 41-44* is/are pending in the application.

4a) Of the above claim(s) *3,6,8-11,17,22,25,27-30,33-39 and 41-44* is/are withdrawn from consideration.

5)☐ Claim(s) _____ is/are allowed.

6)☒ Claim(s) *1,2,4,5,16,18-21,23,24* is/are rejected.

7)☐ Claim(s) _____ is/are objected to.

8)☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

9)☐ The specification is objected to by the Examiner.

10)☐ The drawing(s) filed on _____ is/are: a)☐ accepted or b)☐ objected to by the Examiner.

Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).

Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).

11)☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

12)☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).

a)☐ All b)☐ Some * c)☐ None of:

1.☐ Certified copies of the priority documents have been received.

2.☐ Certified copies of the priority documents have been received in Application No. _____.

3.☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

1) ☐ Notice of References Cited (PTO-892)
2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
3) ☒ Information Disclosure Statement(s) (PTO/SB/08) Paper No(s)/Mail Date *4/13/11*.
4) ☐ Interview Summary (PTO-413) Paper No(s)/Mail Date. _____ .
5) ☐ Notice of Informal Patent Application
6) ☐ Other: _____.

1. A request for continued examination under 37 CFR 1.114, including the fee set forth in 37 CFR 1.17(e), was filed in this application after final rejection. Since this application is eligible for continued examination under 37 CFR 1.114, and the fee set forth in 37 CFR 1.17(e) has been timely paid, the finality of the previous Office action has been withdrawn pursuant to 37 CFR 1.114. Applicant's submission filed on 4/13/11 and 3/28/11 has been entered.

2. The following is a quotation of the second paragraph of 35 U.S.C. 112:

> The specification shall conclude with one or more claims particularly pointing out and distinctly claiming the subject matter which the applicant regards as his invention.

3. Claims 1,2,4,5,16,18-21,23,24 are rejected under 35 U.S.C. 112, second paragraph, as being indefinite for failing to particularly point out and distinctly claim the subject matter which applicant regards as the invention.

Claims 1/18 are indefinite in the recitation of “without compromising the function of the antigen” because it is unclear what this term means or encompasses. The term is not defined in the specification and has no art recognized meaning.

Regarding applicants arguments about how a skilled artisan would interpret said term, the MPEP section *716.01(c) states:*

> ATTORNEY ARGUMENTS CANNOT TAKE THE PLACE OF EVIDENCE

The arguments of counsel cannot take the place of evidence in the record. In re Schulze, 346 F.2d 600, 602, 145 USPQ 716, 718 (CCPA 1965).

There is no disclosure in the specification that the limitation under consideration refers to “neutralizing" or “non neutralizing” antibodies. The cited US Patents do not define the term “without compromising the function of the antigen”. Applicants comments that the limitation under consideration is related to the term “neutralizing" or “non neutralizing” antibodies represent attorney conjecture unsupported by evidence. Regarding applicants comments about the cited passage of the specification, page 3, said passage does not elucidate the meaning of the phrase under consideration. Furthermore, the

phrase referred to in said passage is also not defined in the specification and has no art recognized meaning.

4. The following is a quotation of the first paragraph of 35 U.S.C. 112:

> The specification shall contain a written description of the invention, and of the manner and process of making and using it, in such full, clear, concise, and exact terms as to enable any person skilled in the art to which it pertains, or with which it is most nearly connected, to make and use the same and shall set forth the best mode contemplated by the inventor of carrying out his invention.

5. Claims 1,2,4,5,16,18-21,23,24 are rejected under 35 U.S.C. 112, first paragraph, as failing to comply with the enablement requirement. The claim(s) contains subject matter which was not described in the specification in such a way as to enable one skilled in the art to which it pertains, or with which it is most nearly connected, to make and/or use the invention.

The specification is not enabling for the claimed method wherein the method recites "by means of an in vivo antibody antigen interaction *without compromising the function of the antigen*". Whilst said term is indefinite as per above, if the term is interpreted as including the ability of the molecule to perform its native biologic function, then the function of antigens can be compromised when the antigen is found in an antigen/antibody complex. For example, Mostbock discloses that the properties of IL-2 found in IL-2 /antibody complexes are different (aka compromised, for example see abstract). In addition, the ability of the molecule to function as an antigen is compromised to the extent that the bound antibody masks antigenic determinants on the surface of the protein. Thus, the claimed method reciting the aforementioned functional property is not enabled.

Judge Lourie stated in Enzo Biochem Inc. v. Calgene Inc. CAFC 52 USPQ2d 1129 that:

The statutory basis for the enablement requirement is found in Section 112, Para. 1, which provides in relevant part that:

The specification shall contain a written description of the invention, and of the manner and process of making and using it, in such full, clear, concise, and exact terms as to enable any person skilled in the art to which it pertains, or with which it is most nearly

connected, to make and use the same. . . . 35 U.S.C. Section 112, Para. 1 (1994). "To be enabling, the specification of a patent must teach those skilled in the art how to make and use the full scope of the claimed invention without 'undue experimentation.' " Genentech, Inc. v. Novo Nordisk, A/S , 108 F.3d 1361, 1365, 42 USPQ2d 1001, 1004 (Fed. Cir. 1997) (quoting In re Wright , 999 F.2d 1557, 1561, 27 USPQ2d 1510, 1513 (Fed. Cir. 1993)). Whether claims are sufficiently enabled by a disclosure in a specification is determined as of the date that the patent application was first filed, see Hybritech, Inc. v. Monoclonal Antibodies, Inc. , 802 F.2d 1367, 1384, 231 USPQ 81, 94 (Fed. Cir. 1986), which in this case is October 20, 1983 for both the '931 and '149 patents.

We have held that a patent specification complies with the statute even if a "reasonable" amount of routine experimentation is required in order to practice a claimed invention, but that such experimentation must not be "undue." See, e.g., Wands , 858 F.2d at 736-37, 8 USPQ2d at 1404 ("Enablement is not precluded by the necessity for some experimentation . . . . However, experimentation needed to practice the invention must not be undue experimentation. The key word is 'undue,' not 'experimentation.' ") (footnotes, citations, and internal quotation marks omitted). In In re Wands , we set forth a number of factors which a court may consider in determining whether a disclosure would require undue experimentation. These factors were set forth as follows:

(1) the quantity of experimentation necessary, (2) the amount of direction or guidance presented, (3) the presence or absence of working examples, (4) the nature of the invention, (5) the state of the prior art, (6) the relative skill of those in the art, (7) the predictability or unpredictability of the art, and (8) the breadth of the claims.

Id. at 737, 8 USPQ2d at 1404. We have also noted that all of the factors need not be reviewed when determining whether a disclosure is enabling. See Amgen, Inc. v. Chugai Pharm. Co., Ltd. , 927 F.2d 1200, 1213, 18 USPQ2d 1016, 1027 (Fed. Cir. 1991) (noting that the Wands factors "are illustrative, not mandatory. What is relevant depends on the facts.").

Regarding Wands factors 4,5,7,8, the instant invention recites: “by means of an in vivo antibody antigen interaction *without compromising the function of the antigen*”. Whilst said term is indefinite as per above, if the term is interpreted as including the ability of the molecule to perform its native biologic function, then the function of

antigens can be compromised when the antigen is found in an antigen/antibody complex. For example, Mostbock discloses that the properties of IL-2 found in IL-2 /antibody complexes are different (aka compromised, for example see abstract). In addition, the ability of the molecule to function as an antigen is compromised to the extent that the bound antibody masks antigenic determinants on the surface of the protein. Thus the state of the prior art is that the claimed method reciting the aforementioned functional property is not enabled.

Regarding Wands factors 1-3, the experimental data disclosed in the specification does not address the limitation under consideration. Regarding Wands factor 6, the relative skill of those in the art is high (eg. Ph.D. or M.D.). It appears that undue experimentation would be required of one skilled in the art to practice the instant invention using the teaching of the specification. See In re Wands 8 USPQ2d 1400(CAFC 1988).

Applicants comments about the meaning of the term "by means of an in vivo antibody antigen interaction *without compromising the function of the antigen*" are addressed above. Regarding applicants comments about Mostbock, *the MPEP section 716.01(c) states:*

> ATTORNEY ARGUMENTS CANNOT TAKE THE PLACE OF EVIDENCE

The arguments of counsel cannot take the place of evidence in the record. In re Schulze, 346 F.2d 600, 602, 145 USPQ 716, 718 (CCPA 1965).

The claims under consideration recite: "by means of an in vivo antibody antigen interaction *without compromising the function of the antigen*". Whilst said term is indefinite as per above, if the term is interpreted as including the ability of the molecule to perform its native biologic function, then the function of antigens can be compromised when the antigen is found in an antigen/antibody complex. For example, Mostbock discloses that the properties of IL-2 found in IL-2 /antibody complexes are different (aka compromised, for example see abstract). In addition, the ability of the molecule to function as an antigen is compromised to the extent that the bound antibody masks antigenic determinants on the surface of the protein. Regarding applicants comments, both neutralizing or non-neutralizing antibodies would bind antigen and mask antigenic determinants on the surface of the protein. Thus the state of the prior art is that the claimed method reciting the aforementioned functional property is not enabled.

Regarding Wands factors 1-3, the experimental data disclosed in the specification does not address the limitation under consideration. Regarding Wands factor 6, the relative skill of those in the art is high (eg. Ph.D. or M.D.). It appears that undue experimentation would be required of one skilled in the art to practice the instant invention using the teaching of the specification. See In re Wands 8 USPQ2d 1400(CAFC 1988).

6. The rejection of claims 5/24 under 35 U.S.C. 112, first paragraph, as failing to comply with the enablement requirement for the reasons elaborated in the previous Office Action, paragraph 7 is withdrawn in view of the amended claims.

7. The rejection of claims 1,2,4,5,16,18-21,23,24 under 35 U.S.C. 112, first paragraph, as failing to comply with the written description requirement for the reasons elaborated in the previous Office Action, paragraph 8 is withdrawn of the amended claims.

8. Claims 1,2,4,5,16,18-21,23,24 are rejected under 35 U.S.C. 112, first paragraph, as failing to comply with the written description requirement. The claim(s) contains subject matter which was not described in the specification in such a way as to reasonably convey to one skilled in the relevant art that the inventor(s), at the time the application was filed, had possession of the claimed invention.

There is no support in the specification as originally filed for the recitation of "express a Fcγ receptor" or "expressing the Fcγ receptor" in claims 1 and 18. Regarding applicants comments, said limitation is not found in the claims as originally filed and the cited passages of the specification fail to support the scope of the limitation under consideration. The passages of the specification to which applicant refers disclose FcγRIIB, but there is no disclosure of the other art known classes of FcγR (aka FcγRIIB is not the only member of the genus of FcγR). Thus, there is no support in the specification as originally filed for the scope of said limitation which encompasses FcγR other than FcγRIIB. In addition, said disclosure is limited to the experiments disclosed in the specification which use specific strains of mice and the particular reagents disclosed in said experiments. There is no written description of the scope of the claimed

inventions in the specification as originally filed (aka the claimed inventions constitute new matter).

9. No claim is allowed.

10. Any inquiry concerning this communication or earlier communications from the examiner should be directed to Ron Schwadron, Ph.D. whose telephone number is (571)272-0851. The examiner can normally be reached on Monday-Thursday 7:30-6:00 pm. If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Ram Shukla can be reached on 571 272-0735. The fax phone number for the organization where this application or proceeding is assigned is 571-273-8300.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see http://pair-direct.uspto.gov. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free). If you would like assistance from a USPTO Customer Service Representative or access to the automated information system, call 800-786-9199 (IN USA OR CANADA) or 571-272-1000.

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